## REMARKS

This paper is responsive to the restriction requirement mailed December 3, 2008 ("Restriction Requirement"). Claims 1-18 are currently pending in this application and are subject to a restriction requirement. Claim 18 is also amended to add a comma and new claims 19-21 are presented. Applicants respectfully submit that no new matter is added as support for the claims as amended and new claims exists in the specification and claims as originally filed.

### Response to Restriction Requirement and Election of Species

The Restriction Requirement sets forth the following allegedly distinct inventions:

**Group I:** Claims 2-11 and 18, drawn to a method of regulating ovarian follicular reserves;

**Group II:** Claim 12, drawn to a method of determining the presence or absence of an effect of acceleration of follicle growth;

**Group III:** Claims 13-15, drawn to a method of accelerating the start of growth of quiescent follicles;

**Group IV:** Claim 16, drawn to a method of supporting in vitro follicle development employing a somatostatin agnostic; and

**Group V:** Claim 17, draw to a method of determining the presence or absence of an effect of slowing of follicle growth.

*See* Restriction Requirement at 2. In order to be responsive to the restriction requirement, Applicants hereby elect **Group III**, corresponding to claims 13-15 and new claims 19-21, ***with traverse***. The Restriction Requirement also requires applicants to "elect a single disclosed species of somatostatin agonist analogue with a chemical structure or a SEQ ID NO., with all [] variables clearly identified to represent a single compound." *See* Restriction Requirement at page 4. Applicants hereby elect the following species:

The somatostatin antagonist analogue of general formula **(III)**

$$A^1\text{-cyclo}\{\text{D-Cys-}A^2\text{-D-Trp-}A^3\text{-}A^4\text{-Cys}\}\text{-}A^5\text{-}Y^1$$

**(III)**

in which:

$$A^1 = \text{Cpa},\ A^2 = \text{Pal},\ A^3 = \text{Lys},\ A^4 = \text{Thr},\ A^5 = \text{Nal},\ Y^1 = NH_2$$

Claims 13-15 and new claims 19-21 correspond to this elected species.

**Applicants traverse the restriction requirement for the following reasons.**

The Restriction Requirement states that unity of invention is lacking because "the inventions listed as Groups I-V do not relate to a single general inventive concept because they lack the same or corresponding special technical feature." *See* Restriction Requirement at 3. The Restriction Requirement alleges that the technical feature of Group I is "administering to a patient a medicament comprising somatostatin or one of its agonist analogs" and that said technical feature is demonstrated by U.S. Pat. No. 6,362,164 to Weckbecker ("Weckbecker"). *Id.* Accordingly, the Restriction Requirement argues that because Weckbecker teaches the administration of somatostatin to a subject in need of such treatment, the technical feature does not make a contribution over the prior art and the inventions in groups I-V thereby lack unity.

Claim 1 is directed to "[a] method of regulating an ovarian follicular reserve comprising administering to a patient a medicament comprising somatostatin or one of its agonist analogues." Contrary to the Restriction Requirement's assertion, Applicants' general inventive concept is not "administering to a patient a medicament comprising somatostatin or one of its agonist analogs," (*Id.* at 3) but rather the use of somatostatin or its analogues in preparing a medicament for the regulation (diminishment or acceleration) of the start of growth of follicles in the quiescent stage.

Further, Weckbecker does not anticipate the present invention. Weckbecker refers to a combination of a compound of the somatostatin class and a rapamycin macrolide useful for the prevention or treatment of cell hyperproliferation. *See* Weckbecker Abstract. Applicants' claims are not directed to medicaments comprising combinations of somatostatin, a somatostatin agonist analogue, or a somatostatin antagonist analogue with a compound of another class *nor* the use of the medicament of the invention for the prevention or treatment of cell hyperproliferation.

Weckbecker describes at 9:12-25 that

> the combination of a compound of the somatostatin class and a rapamycin macrolide is indicated for the prevention or treatment of malignant tumor growth, e.g. breast, lung, GEP tumors, pituitary adenomas, lymphomas, etc., for the prevention or treatment of proliferative vascular diseases, e.g. biologically or mechanically induced vascular injury causing intimal thickening, e.g. restenosis, atherosclerosis, vascular occlusion, injury following percutaneous transluminal coronary angioplasty, vascular surgery or transplantation surgery, transplant vasculopathies, for example chronic rejection of various tissues and organs such as heart, kidney, pancreas, lung, liver, bowel, trachea and combined heart-lung.

Accordingly, the regulation (diminishment or acceleration) of the start of growth of follicles in the quiescent stage as taught by Applicants' specification does not fall under the definition of cell hyperproliferation as disclosed above. Therefore, the present invention is not anticipated by Weckbecker.

Finally, Applicants respectfully refer the Examiner to the international search report (with the EPO acting as the ISA) which applied PCT requirements, in particular Rule 13.2 which permits the inclusion of different claim categories in the same application, to find, contrary to the Restriction Requirements assertion, that there was no lack of unity in the claims. Applicants submit that the presently claimed invention comprises a plurality of independent claims in different categories so linked as to form a single general inventive concept. PCT Rule 13.2 states that "[w]here a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding technical features." As discussed above, the claims of the present invention relate to **a single, novel, and general inventive feature**. Accordingly, Applicants earnestly request withdrawal of the restriction requirement.

Applicants also respectfully request rejoinder of the non-elected species in the event that a generic claim is found allowable. Applicants reserve the right to pursue the non-elected subject matter of groups I, II, IV, and V, if necessary, in one or more divisional or continuation applications.

## CONCLUSION

In view of the above remarks, early notification of a favorable consideration is respectfully requested.

Respectfully submitted,

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